

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/160,076	09/24/98	SCOTT	D 308072000110
		HM22/1220	EXAMINER
			WILSON, M
		ART UNIT	PAPER NUMBER
		1633	19
		DATE MAILED:	12/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	09/160,076	Applicant(s)	SCOTT ET AL.
Examiner	Eleanor Sorbello	Art Unit	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 December 2000.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 31-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 31-51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	20) <input type="checkbox"/> Other: _____

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DETAILED ACTION

Continued Prosecution Application

The request filed on 12-8-00, paper number 18, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/160076 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 31-51 are pending and under consideration in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

1. Claims 35, 44 and 50 should be amended to include the phrase --the group consisting of-- after the phrase “selected from” to recite proper Markush language. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 34, 35, 43, 44, 49 and 50 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. It is not sufficient to define DNA solely by its principal biological property, i.e., tolerogenic epitopes of pollen, ragweed, dust mites, clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin, and histocompatibility antigen because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNA with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all DNA's that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to the method claims, adequate description of the methods first requires an adequate description of the materials, i.e. specific DNA sequences, which provide the means for practicing the invention.

3. Claims 34, 35, 43, 44, 49 and 50 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 34, 35, 43, 44, 49 and 50 are directed toward tolerogenic antigens derived from pollen, ragweed, dust mites, clotting factor VIII, acetylcholine receptors, collagen, myelin basic

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protein, thyroglobulin, and histocompatibility antigen because the specification does not teach any epitopes derived from such entities which are tolerogenic or the nucleic acid sequences encoding such epitopes. While the clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin, and histocompatibility proteins and nucleic acid sequences encoding such proteins were known at the time of filing, it was not known which epitopes were "tolerogenic" as claimed. The specification does not teach any tolerogenic epitopes of clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin or histocompatibility proteins. It is also not clear from the specification how clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin, and histocompatibility antigens are "autoantigens" because the term is not defined in the specification and does not have an art recognized meaning. Regarding pollen, ragweed and dust mites, these substances were known allergens, but are made up of more than just protein; therefore, it is unclear what applicants intend to claim. The specification does not teach any antigens of pollen, ragweed or dust mites, provide the nucleic acid sequence of such allergens or teach any tolerogenic epitopes derived from pollen, ragweed or dust mites as claimed. Dust mites and ragweed are whole organisms while pollen is a substance found in any plant. It would require one of skill to determine the tolerogenic epitopes of the exceedingly numerous proteins found in any pollen, ragweed or dust mite. The specification does not provide adequate guidance to transform cells with a vector encoding epitopes from pollen, ragweed, dust mites, clotting factor VIII, acetylcholine receptors, collagen,

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myelin basic protein, thyroglobulin, and histocompatibility antigen such that the epitopes are tolerogenic as claimed.

Therefore, in view of the lack of guidance in the specification regarding how to isolate a nucleic acid sequence encoding a tolerogenic epitope from pollen, ragweed, dust mites, clotting factor VIII, acetylcholine receptors, collagen, myelin basic protein, thyroglobulin or histocompatibility antigens, the state of the art, the examples provided and the breadth of the claims, the ordinary artisan at the time of the instant invention would not have known how to make and/or use the claimed invention with a reasonable expectation of success.

4. Claims 31-51 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31, 41 and 47 and claims dependent therefrom are indefinite because it is unclear which preceding element the term “functional” in line 4 refers. In line 6, the phrase “said fusion immunoglobulin” lacks antecedent basis in the claim. The phrase “derived” is indefinite because the term is not defined in the specification and may have various meanings in the art. It is unclear whether the epitope is isolated from an antigen or has a function similar to the antigen. The phrase “to which tolerance is to be induced” is confusing. If the phrase refers to an antigen to which tolerance is to be induced, it is unclear what characteristics the antigen possess. Are applicants intending to claim an antigen which can induce tolerance? If the phrase refers to tolerance to be induced in the N-terminal variable region, it is unclear what applicants intend to

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claim. The phrase “associated with” found also in claims 34, 42, 43, 48 and 49 is indefinite because the phrase is not defined in the specification and may have various meanings in the art. It is unclear whether applicants intend to claim an antigen which is a cause of disease or allergic reaction or which is a result of disease or allergic reaction. The term may also mean a physical association or bond which is not possible between an antigen and a disease or allergic reaction.

Claim 32 is indefinite because the phrase “the heavy chain” is unclear. Claim 32 is dependent upon claim 31 which may encode a heavy or light chain. Since the vector of 31 may not include the heavy chain and claim 32 does not limit the claim to the heavy chain, it is unclear how to have a vector expressing an epitope next to the heavy chain as claimed.

Claim 34, 43 and 49 are indefinite because the claim requires the epitope is derived from an antigen wherein said antigen is an antigen of pollen, ragweed or a dust mite. However, ragweed and dust mites are whole organisms. Antigens are not derived from whole organisms. Antigens are derived from proteins. Likewise, pollen is made up of more than just protein. It is unclear whether applicants intend to claim antigens derived from proteins within these organisms or antigens derived from a non-protein which causes an immune response which is found within these organisms.

Claims 35, 44 and 50 are indefinite because the term “autoantigen” because an antigen that is recognized as a “self-antigen” in one person may not be recognized as “self-antigen” in a different person. The term “autoantigen” is not defined in the specification and does not have an art recognized meaning; therefore; the term is indefinite. The term “histocompatibility antigen” is

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indefinite. It is unclear whether applicants intend to claim a particular epitope derived from a histocompatibility molecule such as B7 or whether applicants intend to claim an epitope derived from a protein involved in histocompatibility such as antibodies involved in tolerance.

Claim 38 is indefinite because the term “characteristics” is not defined in the specification and may have various meanings in the art as stated in the previous office action. It is unclear whether applicants intend to claim a physical characteristic or a function.

Claim Rejections - 35 USC § 102

5. Claims 31, 32, 37, 39, 40 remain rejected under 35 U.S.C. 102(b) as being anticipated by Zambidis of record (Zambidis et al., Feb. 1, 1993, J. Cellular Biochem., Vol. 9, No. 17, Part B, page 251).

Applicants argue the newly added claims are not anticipated by Zambidis because Zambidis does not teach an antigen which is associated with an autoimmune disease or allergic reaction. Applicants argument is not persuasive because of the indefiniteness rejection regarding the phrase “associated with”. The claim encompasses autoimmune disease or allergic reaction induced by bacteria. Specifically, the disease or reaction may be “associated with” the bacteriophage λ cl protein. The λ cl protein is a foreign protein to animals and would be recognized by the immune system and an immune reaction would occur. Since an immune reaction to a foreign protein is equivalent to an allergic reaction, the λ cl protein meets the limitation of the claim. Therefore, Zambidis anticipates the claims as written by teaching the

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bacteriophage λ cl protein placed at the N-terminus of the IgG1 heavy chain and J588L cells transformed by said construct (see entire abstract). As J588L cells are a myeloma cell line which is a bone marrow tumor cell line, Zambidis clearly anticipates claims 39 and 40. Applicants state the claims in the previous application overcame Zambidis because Zambidis did not teach obtaining tolerance. The claims in the parent application were directed toward methods of inducing tolerance while the instant claims are directed to vectors and cells. The intended use of tolerance as written in the instant claims bears little patentable weight when considering art rejections because the intended use does not change the composition of the claims.

Claim Rejections - 35 USC § 103

6. Claims 31-33, 36, 37, 39-42, 45-48 and 51 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zambidis (Feb. 1, 1993, J. Cellular Biochem., Vol. 9, No. 17, Part B, page 251) in view of Zanetti (Jan. 30, 1992, Nature, Vol. 355, pages 476-477) and Chambers (Feb. 1992, PNAS, USA, Vol. 89, pages 1026-1030).

Zambidis teaches a construct comprising residues of the bacteriophage λ cl protein placed at the N-terminus of the IgG1 heavy chain and J588L cells transformed by said construct (see entire abstract). Zambidis does not teach using a retroviral vector. However, at the time of filing, Chambers teaches expressing lymphokines in peripheral blood lymphocytes (PBL) using a retroviral construct encoding the b-actin promoter/enhancer (page 1029, column 2, "discussion"). Motivation to combine the references is provided by Chambers because the retroviral vector of

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Chambers is an improved method of transfecting reproducing cells such as lymphoid or hemopoietic cells as claimed which would have been recognized by one of ordinary skill in the art at the time of filing. One of ordinary skill would have recognized the ability to improve transduction in lymphoid cells using the retroviral vector and to express the fusion protein in lymphoid cells to study the immune system which was common at the time of filing. The expression of proteins in T-cells and PBLs as taught by Zanetti and Chambers also indicates the transcriptional and translational control regions function in lymphoid cells as claimed providing one of ordinary skill with a reasonable expectation of success.

Applicants argue Zambidis does not provide a reasonable expectation of success and should not be used in the 103 rejection. Applicants argument is not persuasive as is discussed above in the response to arguments presented in the 102 rejection above. Applicants request clarification why Zanetti was used in the previous office action. Zanetti supports the expression of proteins in T-cells and PBL and supports examiners position that one of ordinary skill would have a reasonable expectation of success in obtaining the vectors and cells claimed.

Conclusion

7. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37

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CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

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